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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,906	09/15/2003	Rong-Hwa Lin	A0871.70001US00	1268

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
06/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,906	LIN ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 03/05/2009, has been entered.

Claim 39 has been amended.

Claims 39-41 are pending.

Claims 1-38 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's amendment, filed 03/05/2009.

The rejections of record can be found in the previous Office Action, mailed 09/05/2008.

3. As indicated previously, applicant's submission of an Information Disclosure Statement, filed 02/11/2008, was acknowledged.

The references cited in the Information Disclosure Statement, filed 02/11/2008 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing must be filed within the set period for reply to this Office action.

4. Claims 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable Lazarovits et al. (US 2004/0002450 A1) (1449; #A17) AND/OR Levanon et al. (US 2004/0001839 A1) in view of the well known convention in the art at the time the invention was made to place therapeutic components, including therapeutic antibodies, in a kit for convenience and economy, as evidenced by Anderson et al. (U.S. Patent No. 6,348,581) AND/OR Hockfield et al. (U.S. Patent No. 6,884,619)
and as further evidenced by the Lin 132 Declaration, filed 02/01/2007, filed in priority application USSN 10/051,497, Example 10 of the instant specification and Levanon et al. (US 2005/0152906) essentially for the reasons of record.

Applicant's arguments, filed 03/05/2009, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant assertions that no evidence has been provided to support the claimed feature "homo-multimeric anti-PSGL-1 antibody is selected based on its ability to bind specifically to PSGL-1 on the surface of an activated T cell and to induce apoptosis of the activated T cell".

It appears that applicant is arguing product-by-process limitations with respect to the claimed products.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

However, here the products are described in terms of methods of selecting and not in terms of methods of making. In turn, the method steps do not define the structure of the claimed products.

Furthermore, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144.

With respect to multimers, including homo-multimers, the following is noted.

Lazarovits teach antibody multimers, including, diabodies, triabodies and tetrabodies (e.g., see paragraph [0047] – [0048], [0480] as well as the section on Multimeric Antibodies in paragraphs [0485]- [0508] and Example 10, including paragraph [0652].

Similarly, Levanon teach antibody multimers, including, diabodies, triabodies and tetrabodies (e.g., see paragraph [0047] – [0048], [0060], [0076], [0091] – [0092], [0107] – [0117], [0454], as well as the section on Multimeric Antibodies in paragraphs [0459]- [0482] and Example 10, including paragraph [0633].

Given the teachings of Multimeric Antibodies, including diabodies, triabodies and tetrabodies, the prior art taught homo-multimeric anti-PSGL-1 antibodies.

As pointed out previously and in contrast to applicant's assertions that the prior art antibodies do not meet the claimed features,
the prior art including the evidentiary references provided for the ability of the prior art anti-PSGL-1 antibodies to induce apoptosis / cell death.

The following is reiterated for applicant's convenience.

For example, the Lin 132 Declaration, filed 02/01/2007, filed in priority application USSN 10/051,497, acknowledges that KPL1-specific PSGL-1-specific antibodies can induce apoptosis (e.g., see Exhibit C).

As evidenced by the instant specification, Example 10 on page 33 of the instant specification provides evidence that the KPL-1 antibody and KPL-1 antibody specificity is consistent with the claimed methods of employing anti-PSGL-1 antibodies that induce apoptosis of activated T cells.

Also, as evidenced by the Lin 132 Declaration, filed 02/01/2007 in priority application USSN 10/051,497, the Lin 132 Declaration, filed 02/01/2007, acknowledges that KPL1-specific PSGL-1-specific antibodies can induce apoptosis (e.g., see Exhibit C; including Figure B(2b) on page 10; Figure C(1a) on page 12; Figure C(2a) on page 13).

Therefore, applicant's own disclosure (Example 10 of the instant specification) and own 132 Declaration (Lin Declaration) support the ability of the prior art anti-PSGL-1 antibody to induce apoptosis.

Also, in contrast to applicant's assertions that prior art does not teach all of the features of the claimed invention, such as inducing apoptosis,
the following of record is reiterated for applicant's convenience.

In further evidence of the prior art teachings,
Levanon et al. (US 2005/0152906) teach that cross-linking of anti-PSGL-1 antibody leads to a apoptotic mechanism that contributes to cell killing (e.g., see paragraph [0190], which can be mediated by Fc receptor bearing cells (e.g., see paragraph [0208]) .
In addition, Levanon et al. teach anti-PSGL-1 antibodies that lead to apoptotic mechanisms (e.g., see paragraphs [0041], [0124], [0126], [0127], [0190] – [0195], [0206] – [0212]
and that such anti-PSGL-1 antibodies bind tyrosine-sulfated peptides (e.g., see paragraphs [0001], [0023], [0028], [0029], [0117] – [0136], [0177] - [0186], [0242] – [0251] and [0271]).
Therefore, the prior art teachings by Larsen et al. of employing antibodies that bind sulfated tyrosines would have the inherent property of inducing apoptosis.

The claimed functional limitations would be intrinsic or expected properties of the referenced PSGL-1-specific antibodies, including recombinant forms thereof (chimeric, humanized) as well as multivalent forms thereof.

The following record is reiterated for applicant's convenience.

Lazarovits et al. teach methods of treating various therapeutic conditions, including inflammation, autoimmunity and cancer, with PSGL-1-specific antibodies (e.g., see entire document, including paragraphs [0055] – [0057]; Summary of the Invention on paragraphs [0059] – [0144]; Detailed Description of the Invention), including the Y1, Y17 and KPL1 epitopic specificities (e.g., see Selectins and PSGL-1 on paragraphs [0029] – [0042]; Summary of the Invention; Detailed Description of the Invention; and Examples), including antibody constructs (e.g., see paragraphs [0474] – [0523]), including multivalent or multimeric antibody constructs (e.g., see paragraphs [0047] – [0052], [0480], [0485] – [0507]; Examples 8 – 16 on pages 38-40).

Although Lazarovits et al. does not teach kits comprising "instructions" per se,
Lazarovits et al. does teach diagnostic kits comprising anti-PSGL-1 antibodies (e.g., see paragraphs [0140], [0144], [0520] and [0524]) as well as a number of therapeutic utilities encompassing the use of anti-PSGL-1 antibodies (e.g., see paragraphs [0055], [0131] – [0139], [0509] –[0548]).

Levanon et al. teach methods of treating various therapeutic conditions, including inflammation, autoimmunity and cancer with PSGL-1-specific antibodies (e.g., see entire document, including paragraphs [0055] – [0057]; Summary of the Invention on paragraphs [0059] – [0144]; Detailed Description of the Invention), including the Y1, Y17 and KPL1 epitopic specificities (e.g., see Selectins and PSGL-1 on paragraphs [0029] – [0042]; Summary of the Invention; Detailed Description of the Invention; and Examples), including antibody constructs (e.g., see paragraphs [0448] – [0493]), including multivalent or multimeric antibody constructs (e.g., see paragraphs [0047] – [0052], Summary of the Invention on paragraphs [0059] – [117], [0454], [0459] – [0493]; Examples 8 – 16 on pages 36-38).

Although Levanon et al. does not teach kits comprising "instructions" per se,
Levanon et al. does teach kits including diagnostic kits comprising anti-PSGL-1 antibodies (e.g., see paragraphs [0117], [0494] and [0498]) as well as a number of therapeutic utilities encompassing the use of anti-PSGL-1 antibodies (e.g., see paragraphs [0054] – [0055], [0116], [0504] –[0522]).

Therefore, both Lazarovits et al. and Levanon et al. teach multimeric anti-PSGL-1 antibodies comprising two polypeptides and a heterologous amino acid sequence encompassed by the claimed invention.
As noted above, both Lazarovits et al. and Levanon et al. teach providing such anti-PSGL-1 antibodies in kits as well as describing a number of therapeutic uses for said anti-PSGL-1 antibodies.

Lazarovits et al. and Levanon et al. teach differ from the claimed invention by not describing "instructions for use in kits" comprising antibodies.

First of all, it is noted that where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art.
See In re Ngai and Lin, 70 USPQ2d (Fed. Cir. 2004) and MPEP 2112.01.

In addition, the following has been provided show that it was well known in the art at the time the invention was made by the ordinary artisan to place therapeutic components, including therapeutic antibodies, in a kit for convenience and economy, as evidenced by Anderson et al. (U.S. Patent No. 6,348,581) AND/OR Hockfield et al. (U.S. Patent No. 6,884,619).

Anderson et al. teach kits comprising therapeutic antibodies as well as other ingredients to produce a formulation suitable for administration, including a preference for the kit to comprise instructions for reconstituting and using the antibody (e.g., see columns 14-15, overlapping paragraph).

In a similar vein, Hockfield et al. teach various kits comprising various compounds, including antibodies that include instructional materials which describe the use of the compound to perform described methods (e.g., see VII. Kits on columns 45-46).

One of ordinary skill would have found it obvious to package ingredients and instructions for use into a kit for convenience, economy and the expected benefit of optimizing standardization of preparing and using therapeutic antibodies of interest at the time the invention was made.

It is proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ". See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007).

One of ordinary skill in the art at the time the invention was made would have been motivated to provide multimeric antibodies comprising anti-PSGL-1 antibodies, including those anti-PSGL-1 antibodies with the Y1, Y17 and KPL1 epitopic specificities, in kits comprising said antibodies and instructions for convenience, economy and the expected benefit of optimizing standardization of preparing and using therapeutic antibodies of interest at the time the invention was made, given the teachings of the prior art of inhibiting various inflammatory, autoimmune or cancer conditions targeted by PSGL-1 antagonists, as taught by Lazarovits et al. and Levanon et al. A person of ordinary skill in the art at the time the invention was made would have been motivated by taking the advantages of the specificities and properties of the highly inhibitory properties of the Y1, Y17 and KPL1 anti-PSGL-1 antibody epitopic specificities, including their multimeric forms, to treat various inflammatory, autoimmune and cancer conditions with an expectation of success, since such properties and advantages are consistent with human therapeutic regimens associated with treating said conditions at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to provide antagonistic anti-PSGL-1 antibodies to treat a variety of inflammatory, autoimmune and cancer conditions,
incorporating multimeric antagonistic anti-PSGL-1 antibodies in kits comprising said antibodies and instructions for use would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such kits for convenience, economy and the expected benefit of optimizing standardization of preparing and using therapeutic antibodies of interest at the time the invention was made.

Applicant's arguments have not been found persuasive.

5. No claim allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

Primary Examiner
Technology Center 1600
Art Unit 1644
June 17, 2009